UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,155	12/15/2003	Nicholas A. Sceusa	SCEUSA3A	2090

1444 7590 01/17/2006

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	10/734,155	SCEUSA, NICHOLAS A.	
	Examiner	Art Unit	
	JOHN PAK	1616	

All participants (applicant, applicant's representative, PTO personnel):

(1) *JOHN PAK*. (3)_____.

(2) *ANNE KORNBAU*. (4)_____.

Date of Interview: *13 January 2005*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *Ms. Kornbau faxed a draft claim amendment proposal. A copy of the fax is attached hereto*.

Claim(s) discussed: *All*.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant's proposed amendment and remarks were discussed. Ms. Kornbau asked whether the change to claim 1 overcomes the rejections of record. The Examiner stated that the issue of lack of enablement with respect to numerous unrelated diseases still remains. Ms. Kornbau asked what would be needed and the Examiner replied that applicant would need to submit objective evidence of enablement with respect to the numerous unrelated diseases that are readable on the elected invention, i.e. method for inhibiting the calcium ion excitation secretion cascade by administering the claimed metal ion to an animal suffering from an autoimmune disease which causes secretions and eruptions via the calcium cascade. Ms. Kornbau asked whether the Examiner would enter an after-final amendment with such additional evidence and the Examiner stated that that was unlikely.

DRAFT

THIS IS NOT A COPY OF CLAIMS
Attachment to Interview Summary

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: SCEUSA3A

In re Application of:	)	Confirmation No.: 2090
Nicholas A. SCEUSA	)	Art Unit: 1616
Appln. No.: 10/734,155	)	Examiner: John D. Pak
Filed: December 15, 2003	)	Washington, D.C.
For: METHODS AND COMPOSITION...	)	January 4, 2006

REPLY: AMENDMENT AND REMARKS

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop **AF**
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Replying to the Office Action mailed November 14, 2005, please amend as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Attachment to Interview Summary

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A method for inhibiting the calcium cascade ~~comprising~~ consisting of administering to an animal in need thereof an effective amount of at least one pharmaceutically acceptable polyvalent metal ion that blocks the calcium cascade.

2. (Original) The method according to claim 1 wherein the metal ions are selected from the group consisting of zinc, copper, magnesium, manganese, iron, and aluminum, and mixtures thereof.

3. (Original) The method according to claim 1 wherein the animal is suffering from an autoimmune disease which causes secretions and eruptions via the Calcium cascade.

4. (Withdrawn) The method according to claim 1 wherein the animal is suffering from rhinitis.

5. (Withdrawn) The method according to claim 1 wherein the animal is suffering from herpes virus infection.

6. (Original) The method according to claim 1 wherein the metal ions are administered through the mouth to the nasal cavity.

7. (Original) The method according to claim 6 wherein the metal ions are in a composition which has a pH of about 4.8 so that the metal ions are delivered across the mucous membranes of the mouth into the nasal cavity.

8. (Original) The method according to claim 7 wherein the composition contains an amino acid as a buffer.

9. (Original) The method according to claim 8 wherein the amino acid is glycine.

10. (Original) The method according to claim 9 wherein the metal ion is zinc.

11. (Original) The method according to claim 10 wherein the metal ions are copper and zinc.

12. (Cancelled)

13. (Withdrawn) A method for inhibiting the formation of histamine by blocking the calcium cascade comprising administering to a patient in need thereof and effective amount of at least one metal ion that blocks the calcium cascade.

14. (New) The method according to claim 1 wherein the metal ion is in a dosage form for delivering a therapeutically effective amount of the metal ion from one anatomical compartment to a contiguous anatomical compartment, said dosage form being designed by the steps of:

Attachment to Internet Summary

(a) selecting a recipient compartment of the human body for delivery of the metal ion, and selecting a contiguous repository compartment of the human body for placement of the dosage form;

(b) determining the pH of both the repository and recipient human body compartments;

(c) selecting a therapeutically effective amount of the metal ion to be used in treatment of the recipient compartment;

(d) wherein the pH of the repository compartment necessary to allow an effective amount of the drug according to the formula:

$$-pH_{(repository)} = \log[\text{repository}] = \frac{NAX}{(T)(2.30R_t)} + \log[\text{recipient}]$$

pH=pH of the repository compartment with the dosage form in place,

N=the average Newtonian viscosity of the compartments' fluids,

A=the surface area of the repository compartment,

X=the distance the drug is to travel,

T=the transport time selected,

R=the universal gas constant 1.987 cal/mole-degree or 8.314 joule/mole, and

log is the logarithm of the concentration of drug in

Attachment to Interview Summary

the repository compartment,

log is the logarithm of the concentration of drug in the recipient compartment,

t=temperature of the body compartment in absolute degrees--normally 310 degrees Kelvin;

selecting a buffering system that will provide sufficient buffering effect in the repository compartment to provide delivery of a therapeutic amount of the metal ion to the recipient compartment by producing a pH difference between the repository and recipient compartments, wherein said buffering system is capable of sustaining the pH difference in the repository compartment for a period of time sufficient for delivery of the metal ion to the recipient compartment;

(e) admixing the therapeutically effective amount of the metal ion together with the components of the selected buffering system, a pharmaceutically appropriate base and inert ingredients, into a desired dosage form.

Attachment to Interview Summary

Attachment to Interview Summary

REMARKS

Claims 1-11, 13 and 14 currently appear in this application. The Office Action of November 14, 2005, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Rejections under 35 U.S.C. 112

Claims 1-3 and 6-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification is said to be enabling only for metal ions that have antimicrobial activity.

This rejection is respectfully traversed. The claims have been amended to recite that the metal ions are pharmaceutically acceptable polyvalent metal ions. Support for this amendment can be found in the specification as filed at paragraphs 32-33.

As described in the specification cited above, the metal ions that are delivered are specifically pharmaceutically acceptable metal ions that block the calcium cascade by swamping it. These polyvalent ions take the place of calcium ions, so that the cascade is interrupted. Calcium acts as a trigger for the kinases that produce the mucous from

goblet cells and sub-mucosal glands associated with rhinitis, and thus produces probable positive charges in mucociliary clearance. The other ions block the kinases by attaching to the kinases but not triggering the kinases. These ions also interfere with mast cell release of histamine, which is associated with allergic reactions rather than viral causes.

Specific polyvalent ions that can be used are Zn^{2+}, Cu^{2+}, Al^{3+}, Fe^{3+}, Sn^{2+} and Mn^{2+}, either alone or in combination with each other. Calcium has a large diffuse electron cloud, and the other ions have smaller, tighter electron clouds. This allows the other ions to slip into spots in the calcium cascade that calcium occupies, and then displace calcium by the law of mass action. Since the ions bear the correct charge, they remain in the nasopharyngeal area after the dosage form is consumed. The polyvalent ion can be any charged polyvalent ions that fit the receptor site.

Contrary to the Examiner's assertion that the claims are directed to almost 80% of the 103 known elements, the claims are really directed to pharmaceutically acceptable polyvalent ions that fit the receptor site, including organic cations or organo-metallic cations that fit the receptor site, and interrupt the calcium cascade because calcium cannot get to the receptor sites.

Attachment to Interview Summary

The present invention provides a method for administering ions that will block the calcium cascade using the Teorell-Meyer gradient. These ions are administered to swamp the calcium ions that occur naturally in the body and thereby inhibit the formation of histamine.

The present invention is directed to a method for treating immune and auto-immune diseases and conditions which cause secretions and eruptions via the calcium cascade. Included in this group are rhinitis, rashes, hives, blistering eruptions, cold sores, and running sores such as the bulbous form of impetigo.

The Examiner alleges that autoimmune diseases are notoriously difficult to treat. However, the claims are not directed to treating all auto-immune diseases, but to treating only those auto-immune diseases that cause secretions and eruptions via the calcium cascade.

One skilled in the art noting that the bulbous form of impetigo can be treated by interrupting the calcium cascade would expect that other such diseases which cause secretions *via* the calcium cascade could also be treated successfully.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Attachment to Interview Summary

Attachment to Interview Summary

This rejection is respectfully traversed. Claim 12 has been rewritten as newly submitted claim 14 to include a description of the dosage form. This dosage form is that claimed in claim 12 of U.S. Patent No, 6,414,033, which has been incorporated by reference in the present application.

Art Rejections

Claims 1-3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kashrina in view of Mandell et al.

This rejection is respectfully traversed. Claim 1, and thus claims 2, 3 and 10, has been amended to recite that the method "consists of." That is, nothing is administered other than at least one pharmaceutically acceptable polyvalent metal ion that blocks the calcium cascade. Kashrina, on the other hand, administers a combination of syntomycin/zinc paste. Syntomycin is an antibiotic originally isolated from cultures of *Streptomyces venequelae* in 1947, but is now produced synthetically. It acts by interfering with bacterial protein synthesis and is mainly bacteriostatic. Kashrina applies the paste onto the skin, where it disinfects skin and stops oozing lesions and eliminates hyperemia. There is nothing in either Kashrina or Mandell et al. that would suggest to one skilled in the art that a polyvalent metal salt alone would be useful in treating impetigo. It is not known

which of the components of the Kashrina paste causes these effects, and there is absolutely no recognition of inhibiting the calcium cascade by administering an effective amount of a pharmaceutically acceptable polyvalent metal ion.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action is earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: _____
Anne M. Kornbau
Registration No. 25,884

AMK:srd
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\G\Gels\Sceusa3A\Pto\DRFT AMD 04 JAN 06.doc

Attachment to Interview Summary